

REMARKS

Applicant respectfully requests reconsideration.

Applicant has amended the specification to correct a typographical error.

Claims 80-100 were previously pending and are still pending and under examination in this application. Claims 80 and 89 have been amended to correct typographical errors and to clarify claim language.

No new matter has been added.

Claim Rejections – 35 U.S.C. § 103

The Examiner has rejected claims 80-100 under 35 U.S.C. § 103 as being obvious over Gregg (WO 98/50028 A1). According to the Examiner, Gregg teaches the elected species identified as BMS-201,238 in a pharmaceutical composition. The Examiner asserts that “Gregg teaches a method of lowering serum lipid levels cholesterol and/or triglycerides, inhibiting and/or treating hyperlipidemia, hyperlipemia, hyperlipoproteinemia, hypercholesterolemia and/or hypertriglyceridemia, and/or preventing, inhibiting or treating atherosclerosis, pancreatitis, hyperglycemia or obesity.... comprising administering the compounds of claim 1....”. The Examiner states that “atherosclerosis and diabetes are recognized to have inflammatory components”. According to the Examiner, Applicant has admitted on the record that the practice of “one method for tissue type is exactly the same as practicing it for another tissue type” and therefore the claimed invention is obvious over Gregg.

Applicant respectfully traverses the rejection. The Examiner has improperly relied on Applicants so-called ‘admission’ in rejecting the claims and has not made a *prima facie* case for rejecting the claims.

Gregg teaches administering MTP inhibitors in combination with a fat soluble vitamin to subjects having atherosclerosis. Gregg’s teaching is based on what was already known in the art namely, that MTP binds and transfers lipids to apoB, and that such transfer can lead to atherosclerosis and aberrant fat metabolism. Gregg does not teach or suggest that MTP mediates inflammation or that MTP inhibitors have anti-inflammatory properties.

Applicant was the first to demonstrate a separate and distinct function of MTP. Specifically, Applicant demonstrated that MTP binds and transfers phospholipid to CD1-d. This results in activation of T cells and in inflammation. These effects (and the clinical possibilities that flow from these effects) were neither taught nor suggested by Gregg. Based on the teachings of Gregg, one of ordinary skill in the art would not expect that MTP inhibitors inhibit inflammation or that MTP inhibitors may be used to treat the inflammatory disorders recited in the instant claims.

Respectfully, any suggestion that it would have been obvious, based on Gregg, to administer a MTP inhibitor to a subject having any disorder other than lipid metabolism disorders, atherosclerosis, pancreatitis, hyperglycemia or obesity is an improper application of hindsight based on Applicant's disclosure. Applicant notes that "it is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one skilled in the art." In re Wesslau, 353 F.2d 238, 241, 147 USPQ 391, 393 (CCPA 1965); see also In re Mercer, 515 F.2d 1161, 1165-66, 185 USPQ 774, 778 (CCPA 1975); In re Geiger, 815 F.2d 686, 2 USPQ2d 1276 (Fed. Cir. 1987).

The Examiner asserts that obviousness arises from an admission by the Applicant during prosecution that "'one method for tissue type is exactly the same as practicing it for another tissue type' and therefore 'it is deemed that the methods are obvious 35 USC § 103(a).'" Respectfully, the 'admission' is mischaracterized by the Examiner. Applicant's argument in response to the Restriction Requirement that there is a common pathway and mechanism that unites the presently claimed invention is based on Applicant's discovery of a separate and distinct function of MTP. That mechanism was newly discovered by the Applicant, was neither known nor suggested in the prior art, and Applicant has made no such admission that this newly discovered pathway/mechanism was known in the prior art. Indeed, Applicant has declared this to be their invention as claimed in claims 80-100.

In view of the foregoing, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 80-100 under 35 U.S.C. § 103.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is kindly requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

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Respectfully submitted,

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